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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/101,423	11/27/1998	PHILIP S RUDLAND	WPT-0114-PUS	9634

7590 12/04/2001
WILLIAM G CONGER
1000 TOWN CENTER
TWENTY SECOND FLOOR
SOUTHFIELD, MI 48075

EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/04/2001

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/101,423

Applicant(s)

RUDLAND ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-31 is/are pending in the application.
- 4a) Of the above claim(s) 8-10,12-14,20-22,24-28,30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,11,15-19,23 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Amendment/Response filed 9-19-01 is acknowledged.
2. Amendments to the specification and to the claims 1, 2, 4, 6, 7, 11, 15-17, 23, and 29 have been entered.
3. Claim 3 has been cancelled.
4. Claim 16 as amended depends on claim 13 that is a non-elected invention. Accordingly, it has been considered a non-elected invention. Claims 8-10, 12-14, 16, 20-22, and 24-28 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.
5. This application contains claims 8-10, 12-14, 16, 20-22, and 24-28 drawn to an invention non-elected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
6. Claims 1, 2, 4-7, 11, 15, 17-19, 23, and 29 pertaining to SEQ ID NO 4 are under consideration.
7. Claim 7 is objected to because it recites non-elected embodiments, SEQ ID NO 1, SEQ ID NO 2, SEQ ID NO 3, SEQ ID NO 5, and SEQ ID NO 6.
8. Claim 1 is objected to because of the following informalities: the word "cites" in line 4 of step (i) should be spelled "sites".

9. Compliance With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2) (for example claims 6 and 11 and pages 13-16 of the specification).

It is noted that while a CRF and paper copy of sequence listing has been submitted, the sequences in the specification and claims are not

Art Unit: 1632

identified by sequence identifiers, as required by 37 C.F.R. § 1.821(a)(2) (d).

Applicants are reminded that 37 C.F.R. § 1.821(a)(2) (d) states:

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Applicants are required to correct the claim 6 to conform to 37 C.F.R. § 1.821(a)(1) and (a)(2) (see MPEP 2422).

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 17 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record set forth in the previous office action of 3-16-01.

Response to Arguments

Applicant's arguments filed 9-19-01 have been fully considered but they are not persuasive. It is noted that applicants have argued that since the DNA sequence is known, methods based on the met DNA sequence will have required specificity to target the DNA. Applicants have listed several articles in the response, however, they have not provided copies of any of the articles, therefore, the teachings of the cited articles or their relevance to the claimed invention can not be ascertained. It is noted that several enablement issues were raised in the previous office action regarding the unpredictability and undue experimentation of the

Art Unit: 1632

claimed invention. However, the applicants have not addressed any of these issues. Furthermore, it is reiterated that the specification does not provide any guidance as to how the claimed medicament would have been prepared, what disease would have been treated, what doses would have been administered, and whether treatment of any disease would have been resulted after the administration of the claimed medicament . It is noted that the only description provided by the specification is on page 19 (last 6 lines) and page 20, which indicates that oligonucleotides could be used for blocking the expression the function of a regulatory DNA in a cancer.

12. Claims 1-5, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method wherein a fragment of human DNA of less than 1.5 kb in length, wherein said human DNA is obtained from malignant, metastatic cancer cells, wherein said fragment of human DNA is tagged at both ends with double-stranded synthetic oligonucleotides, and wherein said double stranded oligonucleotides provide restriction enzyme and unique PCR primer sites, is transfected into rat mammary epithelial cells, Rama 37, transformed Rama 37 cells are injected into mammary glands of rats, rats injected with transformed Rama 37 cells are selected in which metastasizing tumors have been identified, and the regulatory DNA that induces metastasis are isolated and recovered from the metastasis tissue of the rats, does not reasonably provide enablement for other claimed embodiments for reasons of record set forth in the previous office action of 3-16-01. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Response to Arguments

Applicant's arguments filed 9-19-01 have been fully considered but they are not persuasive. It is noted that claim 1 as amended recites that the regulatory DNA is not expressed as an mRNA and that the human DNA fragment has been tagged

Art Unit: 1632

at both ends with a double stranded synthetic oligonucleotides that provide restriction enzyme and unique primer sites. It is noted that the applicants have argued, "To support a rejection for non-enablement.....in view of the well structured specification and its preemptive enablement, the office must cite references which show, *inter alia*, that the specific model utilized here does not translate into other models". In response applicants' are directed to last paragraph on page 6 of the previous office action and continued into entire page 7. It is noted that the office action discusses the enablement based on sound scientific reasoning and applicants have ignored to address these issues. Furthermore, in the first full paragraph on page 7, article by Ilyas et al was discussed. Again applicants completely ignored the issues raised in the rejection. Accordingly, office has provided sound scientific reasoning supported by scientific article in support of the enablement rejection and therefore, the enablement rejection is maintained.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-7, 11, 15, 17-19, 23, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear as to what is being qualified by the amendment added in line 2 of step (i). It is noted that the phrase "which have been tagged....." has been added after cells, however it is not clear as to how the cells have been tagged.

Claim 6 recites the limitation "the double-stranded synthetic oligonucleotides tag" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim because the term "a double-stranded synthetic oligonucleotides tag" has not been recited before.

Claim 6 is vague and indefinite because it is unclear as to which of the oligonucleotides, the phrase "has the following oligonucleotide sequence" is

intended to represent, since two oligonucleotides are recited in the claim. Recitation of the SEQ ID NO of the oligonucleotides is suggested.

Claim 7 is vague and indefinite because it is unclear as to what is qualified by the term "consisting essentially of" in line 2.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

16. Claims 15, 18, and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al (Biochemical Society Transactions 24: 345S, 1996).

Chen et al teach a method of identifying regions of human DNA responsible for metastasis in breast cancer. They teach Rama 37 cell that are transfected with tagged DNA fragments isolated from a metastatic transformed cells. The DNA fragments were tagged with 45mer synthetic oligonucleotides to aid the rescue the transfected DNA. The cell lines created by the method were injected into rats and the tissues of the rat were examined for the development of metastatic growth (see the first two paragraphs in the left column). Table 1 teaches the results of the study. They also teach amplification of the cellular DNA isolated from cell lines developed from the rat metastatic tissues (see the last paragraph) in right column.

Accordingly, the invention of claims 15, 18, and 19 are anticipated by Chen et al.

17. Claims 15 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Sasaki et al (US 5808024, 9-15-1998, filing date 6-7-1995).

Sasaki et al teach a DNA sequence nt 3825-3842 of which have 100% sequence similarity with nt 827-844 of SEQ ID NO 4. Accordingly, the nt 3825-3842 can be used as a specific probe for SEQ ID NO 4 and therefore anticipate the inventions of 15 and 23.

It is noted that although claims 7 and 11 recite a functional language for the DNA sequence, the only characteristic for a probe to be specific for a particular DNA is its sequence characteristics and therefore, the probe corresponding to nt 3825-3842 would be specific for the DNA recited in claims 7 and 11.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instruction, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703)

Application/Control Number: 09/101,423

Page 8

Art Unit: 1632

305-6608. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Kay Pinkney whose telephone number is (703) 305-3553.

Ram R. Shukla, Ph.D.



DAVE T. NGUYEN
PRIMARY EXAMINER